

Opsumit® REMS

(Risk Evaluation and Mitigation Strategy)

Guide for Females Who Can Get Pregnant

Information to help you throughout your treatment with Opsumit



*Please see accompanying full Prescribing Information, including **BOXED WARNING** for birth defects, and Medication Guide.*

Reference ID: 3890030

ACTELION
Pathways®

Table of contents

What is Opsumit® (macitentan)?2

What are the serious risks of Opsumit? 3

What is the Opsumit REMS Program?.....3

How do I enroll in the Opsumit REMS Program?.....3

What are the Opsumit REMS Program requirements for me?4

What are my birth control options?.....5

How will I receive Opsumit?.....6

Your steps to treatment with Opsumit.....7

What is Opsumit?

Opsumit is a prescription medicine used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

Opsumit can improve your ability to exercise, improve some of your symptoms, and help slow down the progression of your disease. Opsumit can also lower your chance of being hospitalized for PAH.

It is not known if Opsumit is safe and effective in children.

What are the serious risks of Opsumit?

Opsumit can cause **serious birth defects** if taken during pregnancy. Women must not be pregnant:

- When they start taking Opsumit,
- While taking Opsumit, or
- Within one month of stopping Opsumit

What is the Opsumit REMS (Risk Evaluation and Mitigation Strategy) Program?

The Opsumit REMS is a program to tell patients and healthcare providers about the risk of serious birth defects when taking Opsumit. This program is required by the Food and Drug Administration (FDA). All females must enroll in the Opsumit REMS Program to receive Opsumit. REMS stands for **Risk Evaluation and Mitigation Strategy**.

How do I enroll in the Opsumit REMS Program?

There are several steps you must take:

1. Read this *Opsumit REMS Guide for Females Who Can Get Pregnant* and the *Opsumit Medication Guide* (which comes with your medicine)
2. Ask your healthcare provider any questions you have about taking Opsumit and the Opsumit REMS Program
3. Make sure you understand:
 - The benefits and risks of Opsumit
 - How to enroll and take part in the Opsumit REMS Program
4. Complete and sign the *Opsumit Patient Enrollment and Consent Form* with your healthcare provider. Your healthcare provider will fill out most of the enrollment form for you and will send the form to *Actelion Pathways*®. *Actelion Pathways* runs the Opsumit REMS Program

What are the Opsumit® REMS Program requirements for me?

- Females who can get pregnant must have a negative pregnancy test before starting Opsumit, each month for as long as they are being treated with Opsumit, and for one month after they stop taking Opsumit. Your healthcare provider will order the pregnancy tests for you
 - You are considered a female who can get pregnant if you:
 - Have entered puberty, even if you have not started your period, and
 - Have a uterus, and
 - Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)
- You must use reliable birth control at all times when taking Opsumit and for one month after stopping Opsumit. Your birth control options are listed on page 5
- Do not have unprotected sex
- Talk to your healthcare provider right away if you have unprotected sex, if you think your birth control has failed, or if you think you are pregnant. If so, your healthcare provider may discuss medical options with you (eg, emergency contraception). Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you are pregnant
- Opsumit is not available at your local pharmacy. You must receive Opsumit through a certified pharmacy (sometimes called a specialty pharmacy)
 - Your pharmacy will call you every month to ask if you have completed a pregnancy test before shipping your Opsumit to your home or another shipping address you choose
- You may not receive your Opsumit refill on time if you do not confirm with the pharmacy that you have had your monthly pregnancy test

What are my birth control options?

Your healthcare provider will talk with you about your birth control options before starting Opsumit. Ask your healthcare provider if you have any questions. Tell your healthcare provider if you want to change your birth control.

You must choose one of the 4 options listed below. More than one birth control method might be needed every time you have sex.

Acceptable birth control options

Option 1	OR	Option 2	OR	Option 3	OR	Option 4
One method from this list: Standard intrauterine device (Copper T 380A IUD) Intrauterine system (LNg 20 IUS: progesterone IUS) Progesterone implant Tubal sterilization		One method from this list: Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection		One method from this list: Diaphragm with spermicide Cervical cap with spermicide PLUS One method from this list: Male condom		One method from this list: Partner's vasectomy PLUS One method from this list: Male condom Diaphragm with spermicide Cervical cap with spermicide Estrogen and progesterone oral contraceptives ("the pill") Estrogen and progesterone transdermal patch Vaginal ring Progesterone injection

How will I receive Opsumit®?

- Opsumit is available only through a certified pharmacy (sometimes called a specialty pharmacy).
- *Actelion Pathways*® provides support and services that help patients with their PAH medicines. Once you are enrolled, a Patient Case Manager will work with you to get your Opsumit prescription filled by a pharmacy
 - Before your first prescription is filled, the pharmacy will call you to schedule a shipment of Opsumit that will come right to your home
 - The *Opsumit Medication Guide* will be included in the package
 - Read the *Opsumit Medication Guide* each time you receive it. Important information may have been added or changed

For a list of certified pharmacies, please call *Actelion Pathways* at **1-866-ACTELION (1-866-228-3546)**.

Your steps to treatment with Opsumit

Use this helpful checklist to get started with Opsumit and to stay on track during your treatment.

FIRST:

- ☐ Review the *Opsumit REMS Guide for Females Who Can Get Pregnant* and the *Opsumit Medication Guide* with your healthcare provider
- ☐ Make sure you understand the risks and benefits of taking Opsumit
- ☐ Go for your pregnancy test
- ☐ Enroll in the Opsumit REMS Program

NEXT:

- ☐ Expect a call from your Patient Case Manager. He or she will help you get your Opsumit prescription filled by one of the certified pharmacies
- ☐ Expect a call from the pharmacy to schedule your first shipment

EVERY MONTH:

- ☐ Read the *Opsumit Medication Guide* that comes with every shipment
- ☐ Use reliable birth control method(s) agreed upon with your healthcare provider—during treatment and for one month after you stop taking Opsumit
- ☐ Complete the monthly pregnancy test ordered by your healthcare provider
- ☐ Expect your pharmacy to call you every month to ask if you had a pregnancy test in the last month before it reorders your Opsumit. The refill may not be done on time if you’ve not had your pregnancy test
- ☐ Do not get pregnant. Tell your healthcare provider right away if you:
 - Have unprotected sex
 - Think that your birth control failed
 - Miss a menstrual period
 - Think you are pregnant



The Opsumit® REMS Program is administered by *Actelion Pathways*®.

You can reach *Actelion Pathways* by calling toll free at
1-866-ACTELION (1-866-228-3546).

For more information about the Opsumit REMS Program,
please visit www.OpsumitREMS.com.

*Please see accompanying full Prescribing Information, including
BOXED WARNING for birth defects, and Medication Guide.*

